PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 553353C	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/001490	International Filing Date *(day/month/year)* 11 November 2003	Priority Date *(day/month/year)* 11 November 2002

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61K 31/167, 31/365, 31/7048, 31/4184, A61P 31/00

Applicant

SCHERING-PLOUGH PTY. LIMITED et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of the report
24 May 2004	1 June 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer TERRY SUMMERS Telephone No. (02) 6283 3126

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

[redacted]national application No.
PCT/AU2003/001490

I. Basis of the report

1. With regard to the **elements** of the international application:*

- [X] the international application as originally filed.
- [ ] the description, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the drawings, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] contained in the international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-29	YES
	Claims		NO
Inventive step (IS)	Claims	1-29	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-29	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Citations

The opinion has considered the following documents cited in the International Search Report:

D1: Commonwealth of Australia Gazette, No. NRA 9

D2: Commonwealth of Australia Gazette, No. NRA 12

D3: Stevenson CR et al

D4: Derwent Abstract Accession Number 99-081974/08

D5: Derwent Abstract Accession Number 1999-405704/35

D1 discloses an aqueous sheep oral flukicide and broad spectrum drench comprising 1g/L ivermectin and 50g/L triclabendazole, see page 19, left column "Product Name Fasimec® Sheep"

D2 discloses a cattle oral flukicide and broad spectrum drench comprising 2g/L ivermectin and 120g/L triclabendazole see page 11, left column "Product Name Fasimec® Cattle"

D3 discloses the oral and subcutaneous administration of Fasimec® Cattle (comprising 2g/L ivermectin and 120g/L triclabendazole) and Fasimec® Sheep (comprising 1g/L ivermectin and 50g/L triclabendazole) to treat liver fluke and gastro-intestinal nematodes in cattle and sheep respectively. (See page 698).

D4 discloses a veterinary antiparasitic composition comprising avermectin or ivermectin and albedazole in a suspension, emulsion or cream.

D5 discloses an oral composition comprising avermectin and albedazole to treat internal and external parasites, tenia and fluke.

Novelty and Inventive Step

Claims 1-23 encompass an **aqueous micellar formulation** which has to be **suitable** for topical administration, comprising a first active ingredient selected from water insoluble benzimidazoles, salicylanilides in combination with a macrocyclic lactone. The formulation also comprises 100g-400g of veterinary acceptable surfactants, 200g-750g veterinary acceptable water miscible solvents and 50g-350g of water.

Continued in Supplementary Box I

Supplemental Box I

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V

Claims 24-29 encompass a method of treating a parasite infected state in a mammal, wherein the infection comprises liver fluke or nematode or both, by topically applying the composition of claim 1 or claim 22.

The invention defined in claims 1-29 appear to be novel and inventive in light of D1-D5. Even though D1 discloses an **aqueous solution** (Fasimec®), comprising triclabendazole (water insoluble benzimidazoles), in combination with ivermectin (macrocyclic lactone), D1 does not disclose the inclusion of 100g-400g of veterinary acceptable surfactants and 200g-750g veterinary acceptable water miscible solvents. Furthermore D1 does not explicitly disclose an aqueous **micellar** formulation and whether this formulation is suitable for topical formulation.

Therefore as there is no enabling disclosure or suggestion of an **aqueous micellar formulation** comprising a first active ingredient selected from water insoluble benzimidazoles, salicylanilides in combination with a macrocyclic lactone, additionally comprising 100g-400g of veterinary acceptable surfactants, 200g-750g veterinary acceptable water miscible solvents and 50g-350g of water OR the use of said formulation to treat a parasite infected state in a mammal by topical administration, claims 1-29 appear novel and inventive in light of D1-D5.

Industrial Applicability

Claims 1-29 are industrially applicable.